UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,818	11/21/2003	Matthias Stiene	LFS-5021	1342

27777 7590 08/26/2008

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
08/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,818	STIENE ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed November 14, 2006. Claims 1-16 are pending. Claims 1 & 15 have been amended. No new claim has been added.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-2, 4-7, 12 & 15-16** are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al. (US 6,080,116).

In regards to **claim 1**, Erickson et al. discloses a device for extracting bodily fluid, the device comprising:

a penetration member (42, 42'), the penetration member (42, 42') having a channel and being configured for penetrating a target site and subsequently residing within the target site and extracting a bodily fluid sample therefrom; and

a fluid flow regulator (12, 12') disposed within the channel of the penetration member (42, 42'), the fluid flow regulator (12, 12') adapted to reduce bodily fluid flow rate through the penetration member (42, 42');

wherein the channel of the penetration member (42, 42') has a distal end of a predetermined volume; and

wherein the fluid flow regulator (12, 12') is disposed adjacent to the distal end of the channel of the penetration member (42, 42') (see figs. 1-2 & 8; see abstract; see col. 3, lines 41-67; col. 5, lines 17-20 & 43-60; col. 6, lines 40-44).

First the Examiner notes that the distal end of the penetration member can be construed as any distal length of the penetration that has a volume. The Examiner further notes that the term "adjacent" is defined by Webster's II New Riverside University Dictionary (1994) to mean "close to: nearby," "adjoining" or "touching." As such, the Examiner does not observe any inherency from the claim language that would suggest that the distal end of the penetration member should be axially spaced from the fluid flow regulator. Instead, the Examiner notes that the fluid flow regulator is merely disclosed as adjacent the distal end, which, broadly speaking, means that it could be in contact with said distal end. Besides, the outside diameter of the fluid flow regulator of Erickson et al. appears to be near the distal end portion of the penetration member, thus it is adjacent to thereto.

In regards to **claim 2**, Erickson et al. discloses a device wherein the fluid flow regulator (12, 12') is further adapted to minimize bodily fluid flow rate variation through the penetration member (42, 42').

The Examiner notes that the capillary tube 12 of Erickson et al. inherently minimizes body fluid flow rate variation by allowing the fluid to move at a specific unchanging rate dictated by the size (i.e. length and uniform diameter) of the capillary tube 12.

In regards to **claim 4**, Erickson et al. discloses a device wherein the penetration member (42, 42') is configured for penetrating a dermal tissue target site and extracting an interstitial fluid sample therefrom (see col. 5, lines 26-42; col. 7, lines 21-22).

In regards to **claim 5**, Erickson et al. discloses a device wherein the distal end of the channel has an inner diameter in the range 100 µm to 500 µm (see figs. 1-2 & 8).

The Examiner notes that since Erickson et al. teach a capillary tube 12 having a outside diameter of about 140 µm (see col. 5, lines 47-52) and a penetration member having an outside diameter of about 360 µm (see col. 12, lines 64-67); effectively, the inside diameter of the penetration member would be between about 140 µm and about 360 µm.

In regards to **claim 6**, Erickson et al. discloses a device wherein the fluid flow regulator (12, 12') includes a narrow-bore channel and wherein a diameter of the narrow-bore channel is less than a diameter of the distal end of the channel (see figs. 4 & 7-8).

In regards to **claim 7**, Erickson et al. discloses a device wherein the narrow-bore channel has a diameter in the range of 114 µm (see col. 5, lines 47-52).

In regards to **claim 12**, Erickson et al. discloses a device wherein the penetration member (42, 42') and the fluid flow regulator (12, 12') are formed as an integral unit (see figs. 7-8).

In regards to **claim 15**, Erickson et al. discloses a method for extracting bodily fluid from a target site, the method comprising:

providing a device for extracting bodily fluid that includes:

a penetration member (42, 42'), the penetration member (42, 42') having a channel and being configured for penetrating a target site and subsequently residing within the target site and extracting a bodily fluid sample therefrom; and

a fluid flow regulator (12, 12') disposed within the channel of the penetration member (42, 42'), the fluid flow regulator (12, 12') adapted to reduce bodily fluid flow rate through the penetration member (42, 42');

wherein the channel of the penetration member (42, 42') has a distal end of a predetermined volume; and

wherein the fluid flow regulator (12, 12') is disposed adjacent to the distal end of the channel of the penetration member (42, 42');

penetrating the target site with the penetration member (42, 42'); and

extracting bodily fluid from the target site (see figs. 1-2 & 8; see abstract; see col. 3, lines 41-67; col. 5, lines 17-20 & 43-60; col. 6, lines 40-44).

In regards to **claim 16**, Erickson et al. discloses a device wherein the extracting step extracts ISF from the target site (see col. 5, lines 26-42; col. 7, lines 21-22).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 3 & 8-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. ('116) in view of Barrett (US 5,718,676).

Erickson et al. disclose a device, as described above, that fails to teach a device wherein the narrow-bore channel has a diameter that decreases in a stepped manner.

However, **Barrett** teaches that it is known to gradually decrease the inner diameter of a channel in a gradual or stepped manner (see figs. 7A-D).

It is known to increase the internal diameter of a body-fluid carrying channel so as to thereby increase fluid flow through the channel (see abstract; see figs. 1-3; col. 2, lines 30-51; col. 3, lines 40-58 of US 4,563,180 to Jervis et al.); Barrett also teaches that it is known to manufacture inner diameter channels with gradually decreasing or stepped diameters (see figs. 7A-D); since Erickson et al. teach a device that may require negative pressure or compressing to increase the flow of body fluid up into the capillary tube for containment therewithin (no flow through and outside the capillary tube) (see col. 5, lines 56-60; col. 6, lines 6-14; col. 7, lines 34-42), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Erickson et al. with a gradually decreasing or stepped bore diameter as taught by Barrett in order to smoothly or differentially (i.e. in a step-wise

manner) decrease or slow the fluid flow through the capillary tube for containment therewithin.

6. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. ('116).

Erickson et al. disclose a device, as described above, that fails to teach a device wherein the diameter of the distal end of the channel is approximately 300 μm and the narrow bore diameter has a width of 12 μm and a height of 15 μm.

Since Ericson et al. teach a device wherein the penetration member outside diameter is about 360 μm (see col. 12, lines 64-67), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the device of Erickson et al. with a penetration member inside of approximately 300 μm as claimed since such a penetration member may still maintain its outside diameter of 360 μm.

Moreover, since Erickson et al. teach a device for collecting ISF in epidermis, which has a thickness of about 2000-3000 μm (see col. 5, lines 20-25), it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the device of Erikson et al. as modified by above with a narrow-diameter having a height of 15 μm as claimed in order to sample the body fluid from the epidermis.

Even moreover, Erickson et al. discloses a device as modified above that teaches all the limitations of the claim. However, Erickson et al. do not expressly disclose that flow regulator has width of 12 μm. Instead Erickson et al. teach a flow

regulator with a width of 26 μm; for example an inside diameter of 114 μm and an outside diameter of 140 μm.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide device of Erickson et al. with a width of 12 μm as claimed because the Applicant has not disclosed that having a width of 12 μm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Erickson's width and Applicant's invention to have performed equally well with either the width taught by Erickson et al. or the claimed width of 12 μm because the width would perform the same function of bending resistance or rigidity to the flow regulator. Therefore, it would have been prima facie obvious to modify the device of Erickson et al. to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Erickson et al.

7. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. ('116) in view of Kensey (US 6,200,277).

Erickson et al. disclose a device, as described above, that fails to teach a device wherein a surface of the flow regulator includes an anti-thrombogenic coating.

However, Kensey teaches that it is known to provide flow regulator with an anti-thrombogenic coating in order to prevent blood from adhering to the flow regulator's internal walls (see col. 10, lines 23-38).

As such, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the device of Erickson et al. as described above with an anti-thrombogenic coating as taught by Kensey in order to prevent blood from adhering to the tube's internal wall.

8. **Claims 13-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. ('116) in view of Moreno (US 5,354,537).

Although Erickson et al. teach a flow regulator is formed of a polymer with non-thrombogenic properties (see col. 6, lines 18-28) and a penetration member that is configured for quick and efficient penetration of the skin (see col. 6, lines 44-46), Erickson et al. disclose a device, as described above, that fails to teach a device wherein

However, **Moreno** teaches a skin penetration member that made of stainless steel (see col. 4, line 42).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide the device of Erickson et al. with a stainless steel penetration member as taught by Moreno in order to achieve a penetration member that is both biocompatible (i.e. does not rust) and hard enough for a quick and efficient penetration of the skin.

Response to Arguments

9. Applicant's arguments filed November 14, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736